U.S. Environmental Protection Agency
Science Advisory Board
Dioxin Review Panel

Summary Minutes

Date and Time: March 2, 2011, 1:00 – 5:00 p.m. (Eastern Time)

Location: By teleconference

Purpose: The purpose of the teleconference was to continue discussing the draft Dioxin Review Panel report, *SAB Review of EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments* (draft dated 2/9/11)

Attendance:

Members of the EPA Science Advisory Board (SAB) Dioxin Review Panel:

Dr. Timothy Buckley (Chair)
Dr. Harvey Clewell
Dr. Elaine Faustman
Dr. Scott Ferson
Dr. Jeffrey Fisher
Dr. Helen Hakansson
Dr. B. Paige Lawrence
Dr. Michael Luster
Dr. Paolo Mocarelli
Dr. Victoria Persky
Dr. Sandra Petersen
Dr. Arnold Schecter
Dr. Allen Silverstone
Dr. Mitchell Small
Dr. Anne Sweeney

SAB Staff:

Thomas Armitage, Designated Federal Officer
Diana Wong, Designated Federal Officer

EPA Representatives (individuals who requested access to the teleconference):

Stan Barone, EPA Office of Research and Development (ORD)
Norman Birchfield, EPA ORD

Becki Clark, EPA ORD
Vince Cogliano, EPA ORD
Kathleen Deener, EPA ORD
Julie Fitzpatricck, EPA ORD
Lynn Flowers, EPA ORD
Annette Gatchett, EPA ORD
Belinda Hawkins, EPA ORD
Audrey Hofer, EPA ORD
Glenn Rice, EPA ORD
Jeff Swartout, EPA ORD
Linda Teuschler, EPA ORD
Darrell Winner, EPA ORD

Public (individuals who requested access to the teleconference):

Craig S. Barrow, Craig Barrow Consulting
Nancy Beck, OMB
Robert Budinsky, Dow Chemical Company
Heather Burleigh-Flayer, PPG Industries, Inc.
Patricia Kablach Casano, General Electric Company
Kevin Connor, Arcadis, Inc.
John L. Festa
David Fischer, American Chemistry Council
M. Lindsay Ford, Parsons Behle & Latimer
Donald Hassig, NY Cancer Action
Maria Hegstad, Risk Policy Report
Stacy C. Hetz, FDA
Caarl Herbrandson, Minnesota Department of Health
Van P. Hilderbrand, Jr, Sullivan & Worcester, LLP
Laurie Holmes, American Forest and Paper Association
Sarah Irvin, Exponent
Katharine Kurtz, Navy and Marine Corps Public Health Center
Stephen Lester, Center for Health, Environment, and Justice
Yvette W. Lowney, Exponent
Sarah C.L. McLallen, American Chemistry Council
Clarence W. Murray, Center for Food Safety and Applied Nutrition
Olga Naidenko, Environmental Working Group
Resha Putzrath, Navy and Marine Corps
Natalie Paul, AECOM
Pat Rizzuto, BNA, Inc.
Mike Schade, Center for Health, Environment, and Justice
Jay B. Silkworth, GE Global Research Center
Thao Tran
Vera D. Wang, Navy and Maine Corps Public Health Center
Thomas Starr, TBS Associates

Daniele Staskal Wikoff, ToxStrategies, Inc.
Thomas Tripp
David Tundermann
Linda M. Wilson, New York State office of the Attorney General
Timothy C. Wolfson, Babst, Calland, Clements, and Zomnir, PC
Tsedash Zewdie, Massachusetts Department of Environmental Protection

Teleconference Summary:

Convene the meeting

Dr. Thomas Armitage, Designated Federal Officer (DFO) for the Dioxin Review Panel, convened the teleconference at 1:00 p.m. Eastern Time. He identified Panel members who were on the call. He stated that the Panel held a teleconference on March 1st to discuss its draft report and that the discussion of the draft report would continue on this teleconference. Dr. Armitage indicated that meeting materials were available on the SAB web site and that these included: the Federal Register Notice[1] announcing the meeting, meeting agenda,[2] and the Panel's draft report[3].

Review of Agenda

Dr. Timothy Buckley, Chair of the Dioxin Review Panel, reviewed the teleconference objectives and agenda. He thanked Panel members for their discussion of the draft report on the March 1st teleconference. He noted that the responses to charge questions 1-4 in the draft report had been discussed, and that the Panel would next discuss the any changes needed in the responses to charge questions 5 and 6 as well as the executive summary and the letter to the Administrator.

Panel Discussion

Discussion of the responses to charge question # 5

Dr. Buckley called for discussion of the responses to charge question 5. Panel members noted that the report recommended that EPA consider including studies with dioxin like compounds in the weight of evidence discussion of the cancer assessment. Members discussed whether specific studies of dioxin like compound toxicity could be suggested for EPA consideration. Members commented that the Panel had discussed a number of animal studies that could be considered. A member suggested that the text of the report be revised to recommend that EPA consider the Viluksela et al. and possibly other studies that were included in the report references. Panel members agreed and Dr. Buckley asked Dr. Hakansson to provide revised text for the third bullet in the response to charge question 5.1.

The Panel discussed the responses to charge questions 5.2.a and 5.2.b. A member noted that the letter to the Administrator indicated that consideration of TCDD mode of action was an area of deficiency in EPA's report. She questioned whether that statement should be included since mechanism of action was not necessarily needed to assess TCDD risk. A member responded that it was important to provide information concerning non-linear mode of action. He suggested a

clarifying editorial change, moving some text from the response to question 5.2.b to the response to question 5.2.a. Another member noted that it was important to clarify the role of the aryl hydrocarbon receptor, but a larger question was whether this would be needed for the TCDD risk assessment. Members discussed and agreed upon some clarifying editorial changes in the text of charge questions 5.2.a and b. This included rearranging some text and indicating that EPA should provide a discussion of evidence for possible modes of action that include both linear and nonlinear alternatives. Dr. Buckley indicated that, as previously discussed, he would revise the letter to the Administrator to identify two areas of deficiency in the EPA report. These areas were consideration of nonlinear dose-response and uncertainty analysis.

Dr. Buckley noted that in the response to charge question 5.3 the draft report mentioned the possible value of including studies of dioxin like compounds in the weight of evidence for carcinogenicity and asked whether specific studies should be cited. A member noted that the Viluksela et al. studies had been discussed and should be cited in recommendations following charge question 5.1. Dr. Schecter indicated that there were studies in the literature involving the health effects of dioxin like compounds. Dr. Buckley asked Dr. Schecter to identify studies that could be cited and send revised text for the third bullet in the response to charge question 5.3 to the DFO.

The Panel next discussed the response to charge question 5.5.c. A member noted that the response indicated that the use of the Emond model is scientifically justified and clearly described. However, he indicated that this part of the report should mention the Panel's concern about the Hill coefficient (discussed in the response to charge question 3). The Chair asked the DFO to revise the report to note that, as discussed in the response to charge question 3.1.d, the Panel has expressed concern about the value of the Hill coefficient used.

The Panel discussed the recommendation in response to charge question 5.8.a. A member stated that he agreed with public comments indicating that the Panel had mixed policy and scientific advice in this recommendation. Dr. Small suggested revising the text to address this concern. He suggested that the report be revised to indicate that in the absence of a definitive nonlinear mode of action, the linear option results can serve as the baseline for comparison with other estimates. Other Panel members agreed with this suggestion, and Dr. Buckley asked Dr. Small to send revised text to the DFO. A Panel member noted that this change should be carried through to the executive summary and letter to the Administrator.

Dr. Buckley asked whether Panel members had any other comments on the responses to charge question 5. There were no additional comments so Dr. Buckley called for discussion of the response to charge question 6.

Discussion of the response to charge question # 6

The Panel discussed the responses to charge question 6. A member indicated that in the response to charge question 3.2.c, the draft report called for the use of Monte Carlo techniques for uncertainty analysis. He noted that this was not recommended in the responses to charge question 6 and he suggested that the recommendation was not necessary and should be removed

from the response to question 3.2.c. Other members agreed. Dr. Buckley asked the DFO to make this change.

Panel members discussed whether clarifications were needed in the response to charge question 6.1. A member commented that the charge question response should indicate that the panel did not agree with EPA's conclusion that a quantitative uncertainty analysis was not feasible, and that specific methods were suggested to do this. Another member agreed that EPA's argument to not conduct a quantitative uncertainty analysis was not scientifically justified, but he noted that perhaps it could be justified. Dr. Small suggested that the text could indicate that EPA's decision to not do an integrated quantitative uncertainty analysis may be based on grounds of practicality or timeliness. He suggested that the draft report indicate that the panel found that more limited evaluations could be implemented to inform critical issues. Other members agreed and Dr. Buckley asked Drs. Small and Ferson to develop revised text for this section and send it to the DFO. A member also indicated that the recommendation stating that EPA should revise or omit Section 6 of its report be changed to indicate that EPA should revise Section 6 of its report. Members agreed and Dr. Buckley asked the DFO to incorporate this revision.

The Panel discussed the comments on the charge question 6 responses that had been provided by Dr. Hauser on the March 1st teleconference. Dr. Hauser had indicated that the questions listed in the response to charge question 6.2 focused on the issue of overstating risk. He commented that these questions should be revised to consider the point that EPA may be understating risk. Panel members agreed with this comment. Dr. Buckley asked Dr. Small to revise this part of the report to address Dr. Hauser's comments and send the revision to the DFO.

The Panel discussed the recommendation in the response to charge question 6.3. Some members commented that in the recommendation it was not necessary to discuss delay in the assessment. Other members noted that the benefits of undertaking a quantitative uncertainty analysis had been discussed in other places in the draft report and did not have to be addressed in this recommendation. Dr. Buckley suggested that the first sentence of the recommendation could be deleted. Members agreed and Dr. Buckley asked the DFO to incorporate this change.

Discussion of the executive summary

The Panel discussed the executive summary. Members commented that changes in the body of the report should be carried forward to the executive summary. Dr. Buckley indicated that he would review the changes in the body of the report and revise the executive summary to reflect these changes.

Discussion of the letter to the Administrator

The Panel discussed and agreed upon a number of changes in the letter to the Administrator.

- Members agreed to remove the word "major" when mentioning the areas of deficiency in EPA's report. Dr. Buckley asked the DFO to incorporate this change

- Dr. Buckley indicated that, as previously discussed, the letter to the Administrator would be revised to identify two rather than three areas of deficiency in EPA's report and asked the DFO to incorporate this change.
- Members agreed to remove the word "balanced" in various places in the letter to the Administrator, executive summary, and body of the report. Dr. Buckley asked Dr. Faustman to provide this revised text to the DFO.
- Members agreed to remove the recommendation to use Monte Carlo techniques and Dr. Buckley asked the DFO to incorporate this change.
- Drs. Peterson, Lawrence, and Sweeney indicated that the first bullet on the first page of the letter should be revised to indicate a more positive tone consistent with the body of the report. Dr. Buckley asked them to send revised text to the DFO.
- Dr. Sweeney noted that she would provide additional text to the DFO indicating that the co-critical studies addressed the important issue of critical windows of susceptibility.
- The Panel agreed upon revised text expressing agreement with EPA's conclusion that the use of human data should be preferred over animal data for the RfD calculation
- The Panel discussed revising the last sentence in the letter. Dr. Small suggested indicating that the SAB urge EPA to move expeditiously and proficiently to finalize the IRIS assessment for dioxin. Dr. Buckley asked Dr. Small to send revised text to the DFO for this sentence.

Action Items and Next Steps

The Chair thanked the Panel members for their comments on the draft report. He asked them to send their revised text and any other editorial corrections needed to the DFO. He noted that he would work with the DFO to incorporate the necessary changes into the report. The DFO would then send a revised draft to Panel members and request concurrence to send the report to the chartered Science Advisory Board for quality review and final approval on a public teleconference. The DFO then indicated that there were no additional items in the agenda. He thanked Panel members for calling and adjourned the teleconference.

Respectfully Submitted:	Certified as True:
/Signed/	*/Signed/*
_____	_____
Dr. Thomas Armitage	Dr. Timothy Buckley, Chair
Designated Federal Officer	SAB Dioxin Review Panel

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by Panel members during the course of deliberations within the meeting. Such ideas, suggestions and deliberations do not necessarily reflect consensus advice from Panel members. The reader is cautioned to not rely on the minutes to represent final, approved,

consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters or reports prepared and transmitted to the EPA Administrator following the public meetings.

ATTACHMENT A: PANEL ROSTER

U.S. Environmental Protection Agency
Science Advisory Board
Dioxin Review Panel

CHAIR

Dr. Timothy Buckley, Associate Professor and Chair, Division of Environmental Health Sciences, College of Public Health, The Ohio State University, Columbus, OH

MEMBERS

Dr. Harvey Clewell, Director of the Center for Human Health Assessment, The Hamner Institutes for Health Sciences, Research Triangle Park, NC

Dr. Louis Anthony (Tony) Cox, Jr., President, Cox Associates, Denver, CO

Dr. Elaine Faustman, Professor and Director, Institute for Risk Analysis and risk Communication, School of Public Health, University of Washington, Seattle, WA

Dr. Scott Ferson, Senior Scientist, Applied Biomathematics, Setauket, NY

Dr. Jeffrey Fisher, Research Toxicologist, National Center for Toxicological Research, U.S. Food and Drug Administration, Jefferson, AR

Dr. Helen Håkansson, Professor of Toxicology, Unit of Environmental Health Risk Assessment, Institute of Environmental Medicine, Karolinska Institutet, Stockholm, Sweden

Dr. Russ Hauser, Frederick Lee Hisaw Professor, Department of Environmental Health, Harvard School of Public Health, Boston, MA

Dr. B. Paige Lawrence, Associate Professor, Departments of Environmental Medicine and Microbiology and Immunology, School of Medicine and Dentistry, University of Rochester School of Medicine and Dentistry, Rochester, NY

Dr. Michael I. Luster, Professor, Department of community Medicine, West Virginia University Health Sciences Center, Morgantown, WV

Dr. Paolo Mocarelli, Professor of Clinical Biochemistry, Department of Clinical Laboratory, Hospital of Desio-Nuovo Monoblous, University of Milano Bicocca, 20033 Desio-Milano, Italy

Dr. Victoria Persky, Professor, Epidemiology and Biostatistics Program, School of Public Health, University of Illinois at Chicago, Chicago, IL

Dr. Sandra L. Petersen, Professor, Associate Graduate Dean, Department of Veterinary and Animal Sciences, College of Natural Sciences, University of Massachussetts- Amherst, Amherst, MA

Dr. Karl Rozman, Professor, Pharmacology, Toxicology and Therapeutics, The University of Kansas Medical Center, Kansas City, KS

Dr. Arnold Schecter, Professor, Environmental and Occupational Health Sciences, School of Public Health-Dallas Campus, University of Texas, Dallas, TX

Dr. Allen E. Silverstone, Professor, Department of Microbiology and Immunology, Health Science Center, SUNY Upstate Medical University, Syracuse, NY and Adjunct Professor of Environmental Medicine, University of Rochester School of Medicine and Dentistry, Rochester, NY.

Dr. Mitchell J. Small, The H. John Heinz III Professor of Environmental Engineering, Department of Civil & Environmental Engineering and Engineering & Public Policy, Carnegie Mellon University, Pittsburgh, PA

Dr. Anne Sweeney, Professor of Epidemiology, Department of Epidemiology and Biostatistics, School of Rural Public Health, Texas A&M Health Science Center, College Station, TX

Dr. Mary K. Walker, Professor, Division of Pharmaceutical Sciences, College of Pharmacy, University of New Mexico, Albuquerque, NM

SCIENCE ADVISORY BOARD STAFF

Dr. Thomas Armitage, Designated Federal Officer, U.S. Environmental Protection Agency, Washington, DC

Dr. Diana Wong, EPA Science Advisory Board, Science Advisory Board Staff Office, Washington, DC

Materials Cited

The following meeting materials are available on the SAB Dioxin Review Panel Web site, at the Meeting Page

http://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/0E37A426CF25AEC98525780D0059E37E?OpenDocument

[1] Federal Register Notice

[2] Agenda

[3] SAB Review of EPA's Reanalysis of key Issues Related to Dioxin Toxicity and Response to NAS Comments